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(54) Device for Sterilising Endoscopical Channels

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(71) Same as inventor

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(54) Title: DEVICE FOR STERILISING ENDOSCOPICAL CHANNELS

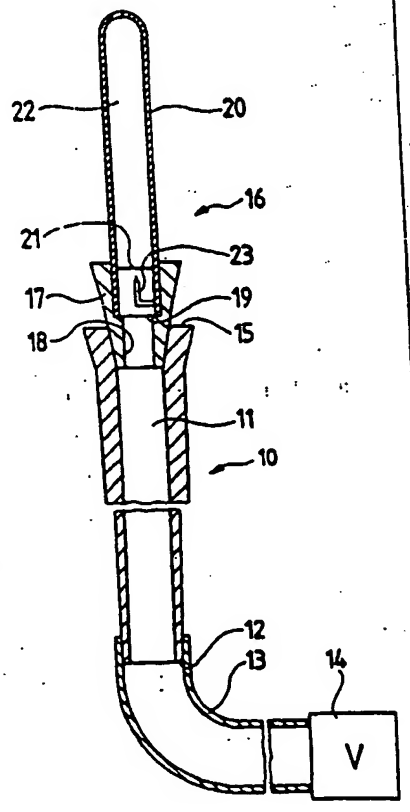
(54) Bezeichnung: STERILISIEREINRICHTUNG FÜR ENDOSKOPKANÄLE

(57) Abstract

A device for sterilising (16) an endoscopical channel (11) to which a vacuum may be applied has an adapter (17) which may be set in a vacuum-tight manner into a free end of the endoscopical channel and which contains a throughbore (18) which extends outwards from the endoscopical channel, and a reservoir (20) which contains a liquid sterilising agent (22) which may be vacuum-vaporised or atomised. The reservoir has an end area provided with an opening which may be set in a vacuum-tight manner into the throughbore of the adapter. A destructible membrane (21) is provided in the reservoir (29) and encloses the sterilising agent in said reservoir. The sterilising device has a needle (23) whose point is oriented from the outside towards the membrane. The membrane (21) and the needle (23) are movable with respect to each other so that during their relative movement the point of the needle pierces the membrane.

(57) Zusammenfassung

Eine Sterilisiereinrichtung (16) für einen mit Vakuum beaufschlagbaren Endoskopkanal (11), mit einem in ein freies Ende des Endoskopkanales vakuumdicht einsetzbaren Adapter (17), in dem eine sich von dem Endoskopkanal nach aussen erstreckende Durchbohrung (18) ausgebildet ist und mit einem Vorratsgefäss (20), in dem ein flüssiges, unter Vakuum vergas- oder zerstäubbares Sterilisiermittel (22) enthalten ist und das einen eine Öffnung tragenden Endbereich besitzt, mit dem das Vorratsgefäss vakuumdicht in die Durchbohrung des Adapters einsetzbar ist, wobei in dem Vorratsgefäss (20) eine zerstörbar ausgebildete Membran (21) vorgesehen ist, die das Sterilisiermittel in dem Vorratsgefäss einschliesst, ist dadurch gekennzeichnet, dass die Sterilisiereinrichtung eine mit ihrer Spitze von aussen auf die Membran weisende Nadel (23) aufweist und dass die Membran (21) und die Nadel (23) relativ zueinander bewegbar ausgebildet sind dergestalt, dass im Zuge der Relativbewegung die Spitze der Nadel in die Membran einstechbar ist.



Sterilising Device for Endoscope Passages

The invention relates to a sterilising device for endoscope passages in accordance with the precharacterising portion of Claim 1.

Conventional endoscopes, i.e. flexible or rigid elongate devices, which may be introduced into the human body, with or without an optical system have one or more passages open at both ends, e.g. flushing or working passages, which open out into the operation field during usage. In order to prevent infection, it is necessary for these passages to be sterilised before each use.

The sterilisation of such passages is, however, difficult, particularly with the flexible endoscopes used e.g. in angiology. Such endoscopes include materials which are heat resistant only to a limited extent so that autoclaving is excluded as a method of sterilisation. Further possibilities, such as treatment with acetylene oxide gas or gamma radiation, require expensive central equipment and are thus not practical, or only to a limited extent.

A change has therefore been made to flush the endoscopes through in situ with hydrogen peroxide. For this purpose, one end of the passage is connected via an adapter to a supply vessel, which is deformable to a limited extent and in which a rupturable ampoule containing hydrogen peroxide is disposed. The passage is acted on by a vacuum via its other end. After the vacuum has built up in the passage the ampoule is broken by compressing the supply vessel walls and the released

For this purpose, one end of the passage is connected via an adapter to a supply vessel, which is deformable to a limited extent and in which a rupturable ampoule containing hydrogen peroxide is disposed. The passage is acted on by a vacuum via its other end. After the vacuum has built up in the passage the ampoule is broken by compressing the supply vessel walls and the released hydrogen peroxide is sucked through the passage thereby effecting the sterilisation. A corresponding method is described in e.g. Hyg. Med. Vol.17, No.12, 1992 on pages 537-543.

Working with this known sterilising device does, however, have a number of disadvantages. One disadvantage is that the destruction of the ampoule by compressing the supply vessel walls is sometimes only possible with the application of a large force and in some cases is not possible at all. A further disadvantage is that small fragments of the ampoule are sometimes sucked into the passage. Finally, it is questionable whether the sterilisation may be conducted in a reproducible manner with the described known supply vessels. Thus it is necessary that the release of the sterilisation agent occurs suddenly through a relatively large opening because it is only in this manner that an adequate atomisation of the sterilisation agent in the passage is possible. Whether such an opening in the ampoule may be achieved in all cases by compressing the supply vessel is questionable.

In order to meet this problem it has been contemplated that the membrane be constructed such that it ruptures

Translator's note:
The words appearing above which are underlined do not appear in the revised version of page 2 which was filed in the International Phase but instead appear on pag 1 of the original text. They have been included in this translation because German word order is different to English word order and their inclusion is therefore necessary to render the translation of the amended pages comprehensible and consistent with the translation of the original text.

automatically after the application of the vacuum. This would be theoretically possible if the membrane is provided with a weakened zone in the region which experiences the greatest deformation due to the vacuum. Such membranes are, however, extremely difficult to manufacture. Problems are caused particularly by the fact that such a membrane must be guaranteed to tear when acted on by a vacuum. On the other hand, the same membrane must ensure a gas-tight enclosure under normal pressure conditions of the hydrogen peroxide contained in the supply vessel, even over relatively long storage periods. The two requirements may only be reconciled with one another with difficulty so that this solution is currently scarcely practicable.

In this connection, reference is also made to EP-A-0452780. In the device disclosed herein, the space to be sterilised is connected via an adaptor to a supply vessel which contains hydrogen peroxide. A destructible membrane is provided in the adaptor and a needle is provided in the supply vessel. When the adaptor is inserted into the supply vessel the needle destroys the membrane and the hydrogen peroxide is released. This device is, however, relatively complex to use.

It is thus the object of the invention to provide a sterilising device which may be simply manufactured and which may be used without problem and in a functionally reliable manner in the course of the sterilisation.

This object is solved with a sterilising device which has the characterising features of Claim 1.

The principle of the solution resides in that a needle is

so arranged in the sterilising device that its tip points from the exterior towards the membrane. The membrane and needle are constructed to be relatively movable in the sterilising device towards one another to the effect that the membrane is punctured by the tip of the needle in the course of the relative movement and releases the enclosed sterilising agent, particularly hydrogen peroxide.

The advantages of the sterilising device in accordance with the invention are clear. Thus the needle arranged in the sterilising device ensures the destruction of the membrane and the desired release of the sterilising agent occurs reliably and without difficulty. Nearly all conventional gas-tight membranes may be used. Various needles can be used for the puncturing, depending on the membrane characteristics, whereby the desired rapid release of the sterilising agent can occur in all cases.

It is e.g. possible to make the membrane from a flexible material which tears when punctured. In such a case a simple compact needle is sufficient for the puncturing.

On the other hand, however, the membrane can also be manufactured from a tear-resistant piercable material. In this modification the needle must then be constructed in the form of a hollow cannula through which the sterilising agent can escape out of the supply vessel into the endoscope passage. The modifications which are possible in this connection will be discussed again below.

Advantageous embodiments of the invention are protected in Claims 2 to 10.

On the other hand, however, the membrane can also be manufactured from a tear-resistant piercable material. In this modification the needle must then be constructed in the form of a hollow cannula through which the sterilising agent can escape out of the supply vessel into the endoscope passage. The modifications which are possible in this connection will be discussed again below.

Advantageous embodiments of the invention are protected in Claims 2 to 10.

It is provided in an advantageous manner in Claim 2 that the needle is fixedly arranged and the membrane is constructed to be movable. The tip of the needle is directed particularly towards a central region of the membrane. The described construction permits a particularly simply and functionally reliable implementation.

Thus it is e.g. possible in accordance with Claim 3 fixedly to connect the supply vessel and the adapter together in a defined position and to construct the membrane in the supply vessel such that it is sucked against the tip of the needle and thereby punctured on application of the vacuum. The sterilisation of the endoscope passage may be conducted, nearly automatically, with a minimum of operational effort with such a sterilising device.

It is possible in accordance with Claim 4 to make the membrane from a material which tears when damaged. When using such a membrane it is ensured in all cases that the release of the sterilising agent occurs suddenly when the

membrane is punctured with the tip of the needle.

However, such suitable membranes generally comprise a different material to the supply vessel and may thus not be manufactured integrally with it. A further embodiment in accordance with Claim 5 thus provides that the supply vessel is constructed of two components to be connected together in a vacuum-tight manner. The membrane, which comprises suitable material, can then be clamped with its edge between the two components in the connection region. The selection of the membrane materials can thus be made independently of the selection of the material of the vessel in an advantageous manner.

In the embodiment which has just been described the needle is generally arranged in the outer portion of the supply vessel. It is however also possible and just as good to construct the needle in accordance with Claim 6 in the adapter. Such a construction has a number of advantages. The main advantage is that the adapter is generally re-used whilst the supply vessel is a disposable item. Since the construction of the needle necessitates a relatively expensive manufacturing process, the manufacturing costs can be substantially minimised in this manner. A further advantage of the separation of the needle and supply vessel resides in that inadvertent piercing of the membrane (e.g. in the event of pressure fluctuations - transport in an aeroplane) is prevented.

A further substantial advantage resides in that the membrane in this embodiment need now no longer be disposed in the interior of the supply vessel. It is instead possible in a further advantageous embodiment in

accordance with Claim 7 to secure the membrane to the edge of the supply vessel by welding or adhesive which constitutes a considerable constructional simplification of the supply vessel.

The previously discussed embodiments relate principally to a sterilising device in which the movement of the membrane with respect to the tip of the needle occurs as a result of the vacuum which is applied.

The movement of the membrane with respect to the needle can, however, occur in some other manner. Thus it is possible in accordance with Claim 8 to construct the supply vessel and adapter such that the supply vessel is movable in a vacuum-tight manner within the adapter. If the needle is arranged in the adapter and the membrane is arranged at a suitable position in the supply vessel it is possible to puncture the membrane by simply pushing the supply vessel into the adapter.

It is particularly advantageous in this embodiment that the selection of the membrane material is subject to virtually no limitations. Since the membrane need no longer deform, it can comprise flexible material, as previously, and also inflexible material. Further possibilities, which are advantageous in this connection, are produced if a continuous hollow cannula, as proposed in Claim 9, is provided as the needle. In this case, in accordance with Claim 10, the membrane can comprise a tear-resistant puncturable material. It is thus even possible in this connection, if desired, to make the membrane from the same material as the supply vessel. When the vacuum is applied the sterilising agent can escape equally well via the passage through the membrane

constituted by the hollow cannula as is the case with a tearable membrane.

The invention will be described in more detail below with reference to a number of drawings illustrating different exemplary embodiments, in which:

Fig. 1 is an overall view of an endoscope passage with a sterilising device positioned thereon,

Fig. 2 is a scrap view on an enlarged scale of the region of the supply vessel carrying the membrane before contact with the needle,

Fig. 3 shows the region illustrated in Fig. 2 after contact of the membrane with the needle,

Fig. 4 is a scrap view on an enlarged scale of the arrangement of a membrane in a two-part supply vessel,

Fig. 5 shows a further possibility for mounting the needle,

Fig. 6 shows an exemplary embodiment in which the needle is constructed as a hollow cannula,

Fig. 7 shows an exemplary embodiment in which the needle is arranged in the adapter,

Fig. 8 is like Fig. 7 and shows an exemplary embodiment in which the needle is arranged in the adapter, but with the difference that the membrane is constructed in the interior of the

supply vessel, and

Fig. 9 finally shows a further exemplary embodiment in which the supply vessel is constructed to be advanceable over a first abutment into the adapter.

An endoscope 10, in which a passage 11 is formed, may be seen schematically illustrated in Fig. 1. The passage 11 is in communication with a vacuum pump 14 via a hose 13 arranged at one end 12 of the endoscope. Arranged at the other end 15 of the endoscope 10 is an exemplary embodiment of the sterilising device 16 in accordance with the invention. The sterilising device 16 comprises an adapter 17, with is inserted in a vacuum-tight manner into the passage 11. The adapter 17 has a through passage 18, whose lower end opens out into the passage 11 and inserted into whose upper end region there is a supply vessel provided with an opening 19 such that the opening 19 is directed towards the passage 11. The supply vessel 20 and the adapter 17 are so constructed that there is a vacuum-tight connection between the passage 11 and the endoscope 10 and the supply vessel 20.

Arranged in the supply vessel 20 is a membrane 21 which defines a sealed region 22 in the vessel 20. Disposed within this sealed region 22 is the sterilising agent.

Hydrogen peroxide is particularly suitable as the sterilising agent. However, e.g. ethylene dioxide could also be considered. Basically all liquid or liquifiable sterilising agents which are atomisable or vaporisable on the sudden application of a vacuum are basically suitable.

Arranged in the supply vessel is a needle 23 whose tip is directed from the exterior towards the membrane 21.

In the state shown in Fig. 1 no vacuum is applied to the passage 11. Figs. 2 and 3 show in detail what occurs when a vacuum is applied.

The region of the supply vessel 20 which carries the membrane 21 and the needle 23 arranged below the membrane may be seen in the detailed view of Fig. 2. If vacuum is now applied, the membrane consisting of a flexible material is deformed in the direction of the arrow 24, moves into engagement with the tip of the needle 23 and tears, as shown in Fig. 3.

After tearing of the membrane, the sterilising agent contained in the previously sealed region 22 suddenly vaporises or atomises and is sucked in this form into the passage 11 in the endoscope 10. Optimal contact between the walls of the passage 10 and the sterilising agent is possible in this manner.

Fig. 4 shows a further exemplary embodiment of a supply vessel 40. It may be seen that the supply vessel 40 comprises an inner portion 21 and an outer portion 42. Clamped between the portions 41 and 42 is a membrane 44 constructed with a thickened edge 43. The outer portion 42 carries a needle 45 whose tip is directed towards the membrane 44.

The arrangement of the membrane in the illustrated manner represents a particularly simple possibility for manufacturing the supply vessel and membran from different materials.

Figs. 5 and 6 show further exemplary embodiments of supply vessels 50 and 60, respectively. In both cases the supply vessels are shown as being of one-part construction again for reasons of clarity. It is, however, also of course possible to clamp the illustrated membranes 51 and 61, as shown in Fig. 4, between two separate supply vessel portions.

Figs. 5 and 6 show different possibilities for the arrangement or construction of the needle. Thus a needle 52, which is carried by a web 53 extending transversely through the supply vessel, may be seen in Fig. 5. This type of fastening of the needle can be more stable than the one-armed fastening shown in Figs. 1-4.

Fig. 6 shows a needle 62 which is constructed as a hollow cannula. The advantage of such a needle resides in the fact that the sterilising agent can also escape through the hollow needle 62 in doubtful cases after piercing the membrane 61. This is particularly advantageous if the membrane does not tear in the desired manner.

Fig. 7 shows a further embodiment of a sterilising device 70 which differs fundamentally from the exemplary embodiments shown above. The endoscope 10 with the passage 11 may again be seen. An adaptor 71 is inserted into the passage 11 at the proximal end 15 of the endoscope 10. The adaptor 71 has a through passage 72 into which the passage 11 opens. Inserted into the upper end region of the through passage 72 is a supply vessel 73 containing the sterilising agent. Thus far there are no differences to the exemplary embodiments shown above.

A substantial difference resides, however, in the fact

that the needle 76 is arranged in the through passage 72 in the adaptor 71. The point of the needle 76 is directed towards a membrane 74 which is welded onto the edge 75 of the supply vessel 73. This arrangement of the membrane 74 at the open end of the supply vessel 73 also represents a difference to the previously shown exemplary embodiments.

If vacuum is applied to the passage 11, the membrane 74 is pulled in the usual manner over the tip of the needle 76 and thereby destroyed. The sterilising agent situated within the supply vessel 73 can escape into the passage 11.

A further exemplary embodiment of the sterilising device 80 is shown in Fig. 8. The needle 81 is arranged in the adaptor 82 in this case also. An important difference to Fig. 7 is that in this case a supply vessel 83 is provided which carries the membrane 84 in its interior. This exemplary embodiment is possibly more difficult to manufacture than that shown in Fig. 7 (under certain circumstances a two-part construction of the supply vesssel is necessary in this case if it is desired to fall back on certain membrane materials). On the other hand, the exemplary embodiment shown in Fig. 8 has the advantage that the membrane is relatively well protected in the interior of the supply vessel 83 and cannot easily be damaged by inadvertent scratches etc.

FIg. 9 shows a further exemplary embodiment of a st rilising device 90 which operates in a fundamentally different manner to the previously shown exemplary mbodiment. An adaptor 91 with a through passag 98, in which a first abutment 92 is constructed, is provided in

this case. A supply vessel 93 is slid into the adaptor 91 against this first abutment 92. The open end of the supply vessel 93 is closed with a membrane 94.

Arranged in the adaptor 91 is a needle 95 whose tip is directed in the usual manner towards the membrane 94.

In the illustrated slid-in position there is a gap 96 between the tip of the needle 95 and the membrane 94.

The abutment 92 is so constructed that the supply vessel may be advanced over this abutment deeper into the adaptor 91 up to a second abutment 97, if a suitable force is applied. In the course of this movement the membrane 94 comes into engagement with the tip of the needle 95 and is destroyed.

In the exemplary embodiment shown in Fig. 9 the destruction of the membrane is thus no longer brought about by the deformation of the memebrane caused by the vacuum. It is effected instead by bodily movement of the membrane 94 against the needle 95.

It will be clear that in this exemplary embodiment shown in Fig. 9 the membrane material no longer need necessarily be of flexible construction. Furthermore, if a hollow needle is selected as the needle, it is even sufficient if the membrane material is merely pierceable.

On the other hand, destruction of the membrane caused by th vacuum is also possible with the exemplary embodiment shown in Fig. 9. Thus the first abutment 92 in the adaptor 91 could be omitted. The tube should then be

introduced into the through passage 98 only so far that experience shows an adequate seal is ensured. The supply vessel 93 is then sucked into the adaptor 91 against the abutment 97 by the application of the vacuum. This possibility would make substantial automation of the sterilisation process possible.

The needles are indicated only schematically in each case in the illustrated exemplary embodiments. They can be constructed as steel needles which are connected to the supply vessel or adaptor, which comprise plastics material, for instance by means of plastic arms. The needles can, however, also consist of suitable plastics material of suitable hardness and tip construction and, if desired, can even be constructed integrally with the supply container or adaptor.

CLAIMS

1. Sterilising device for an endoscope passage to which a vacuum may be applied with an adaptor, which may be inserted in a vacuum-tight manner into a free end of the endoscope passage and in which a through passage is formed extending from the endoscope passage to the exterior, and with a supply vessel, in which a liquid sterilising agent, which is vaporisable or atomisable under vacuum, is contained and which has an end region carrying an opening with which the supply vessel may be inserted in a vacuum-tight manner into the through passage in the adaptor, whereby provided in the supply vessel there is a membrane which is constructed to be destructable and which encloses the sterilising agent in the supply vessel, characterised in that the sterilising device (16,70,80,90) has a needle (23,45,52,62,76,81,95) whose point is directed from the exterior towards the membrane (21,44,51,61,74,84,94) and that the membrane (21,44,51,61,74,84,94) and the needle (23,45,52,62,76,81,95) are constructed to be movable relative to one another such that in the course of the relative movement the tip of the needle (23,45,52,62,76,81,95) may puncture the membrane (21,44,51,61,74,84,94).

2. Sterilising device as claimed in claim 1, characterised in that the needle (23,45,52,62,76,81,95) is fixedly disposed in the sterilising device (16,70,80,90) and the membrane (21,44,51,61,74,84,94) is constructed to be movable with respect to the needle (23,45,52,62,76,81,95), whereby the tip of the needle (23,45,52,62,76,81,95) is directed particularly towards a central region of the membrane (21,44,51,61,74,84,94).

3. Sterilising device as claimed in one of claims 1 or 2, characterised in that the supply vessel (20,40,50,60, 73,83) and the adaptor (17,71,82) are fixedly connectable together in a defined position and the membrane (21,44,51,61,74,84) is constructed of flexible material and so arranged at a distance from the tip of the needle (23,45,52,62,76,81) that it may be sucked over the tip of the needle (23,45,52,62,76,81) and may thus be punctured after the application of the vacuum to the endoscope passage (11).

4. Sterilising device as claimed in one of claims 1-3, characterised in that the membrane (21,44,51,61,74,84,94) comprises material which tears when damaged.

5. Sterilising device as claimed in one of claims 1 to 4, characterised in that the supply vessel (40) is of two-part construction in the transverse direction and the membrane (44) is secured with its edge (43) in the connection region of the two parts (41,42).

6. Sterilising device as claimed in one of claims 1 to 5, characterised in that the adaptor (71,82,91) carries the needle (76,81,95).

7. Sterilising device as claimed in claim 6, characterised in that the membrane (74,94) is disposed on the edge of the supply vessel (73,93).

8. Sterilising device in which the needle (95) is constructed in the adaptor (91) as claimed in one of claims 6 or 7, characterised in that the adaptor (91) and the supply vessel (93) are constructed for vacuum-tight sliding of the supply vessel (93) within the adaptor (91)

and the positions of the membrane (94) and the needle (95) are so selected that the tip of the needle (95) cuts through the membrane (94) during the sliding of the supply vessel (93) into the adaptor (91).

9. Sterilising device as claimed in one of claims 1-8, characterised in that the needle is a hollow cannula (62).

10. Sterilising device as claimed in claims 8 and 9, characterised in that the membrane comprises a tear-resistant puncturable material.

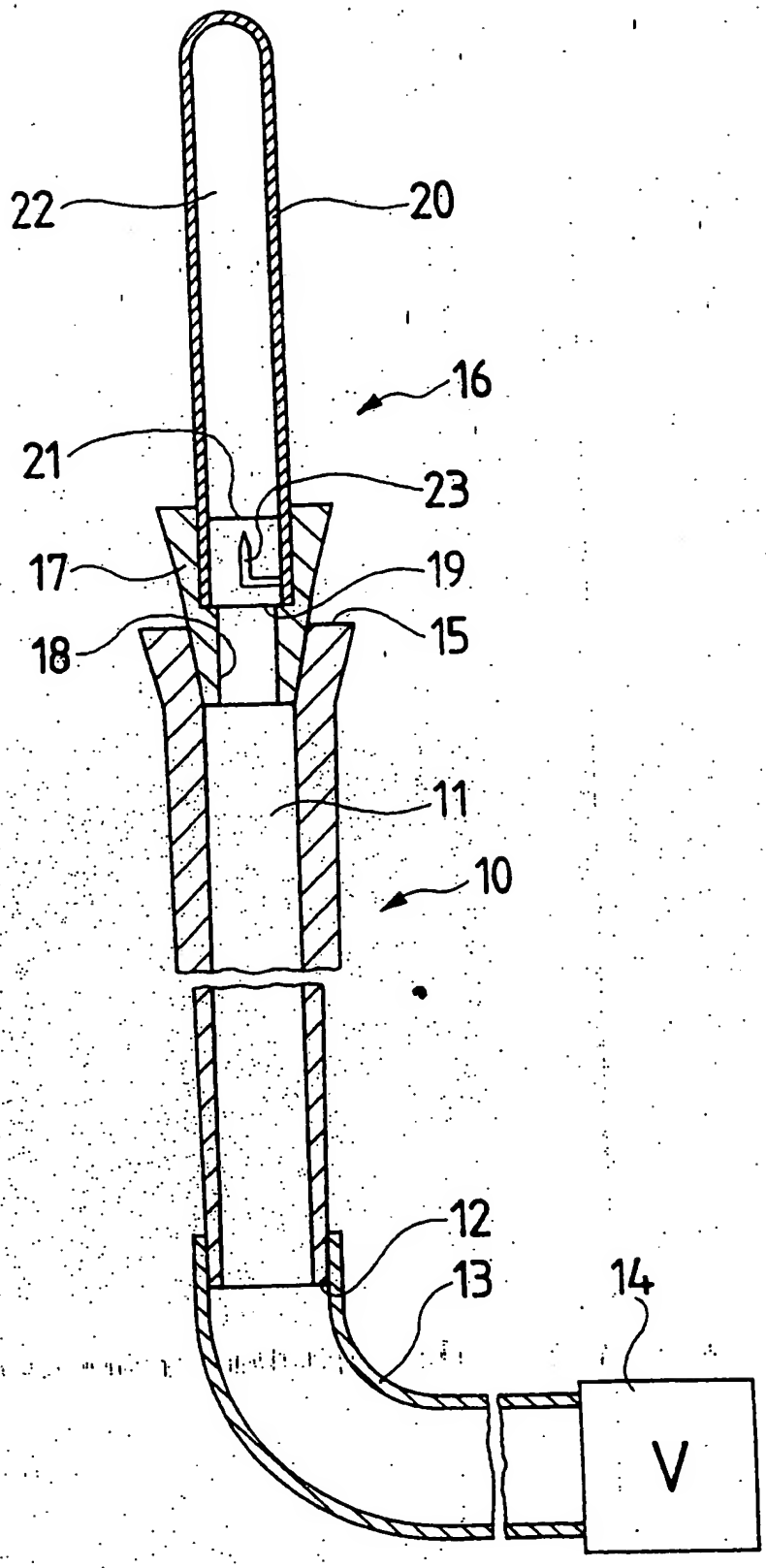


Fig.1

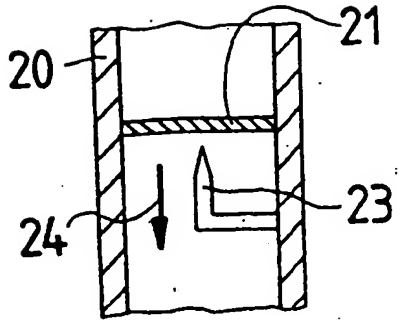


Fig. 2

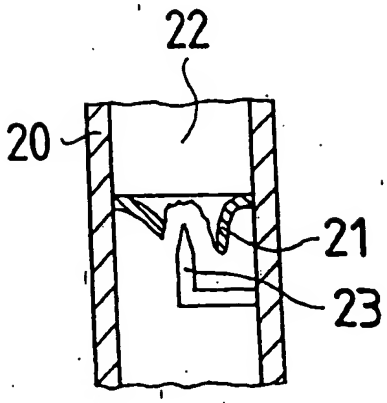


Fig. 3

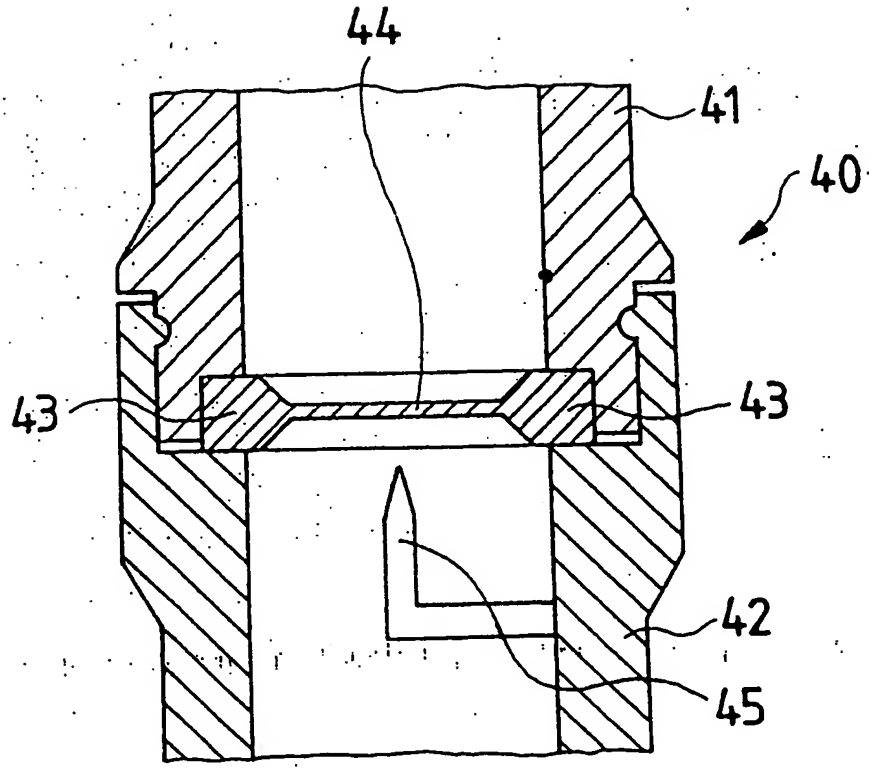


Fig. 4

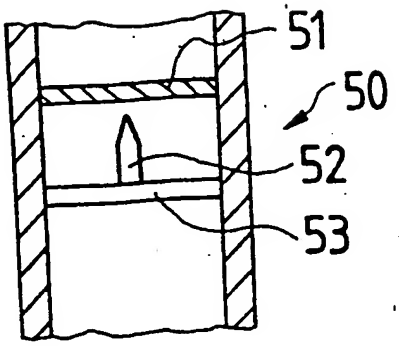


Fig.5

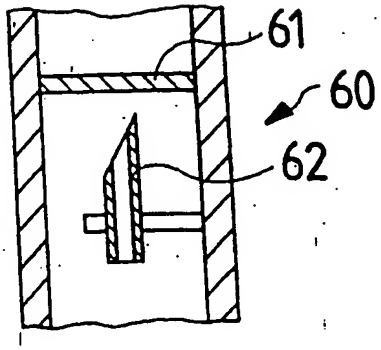


Fig.6

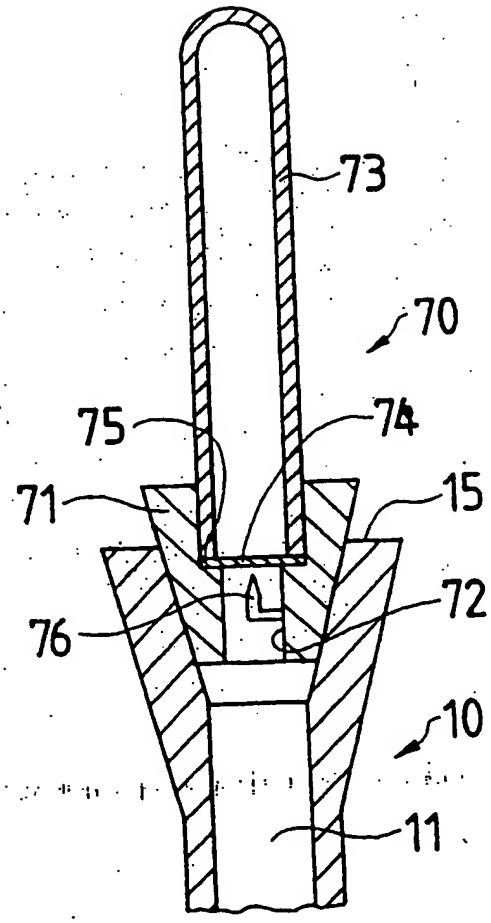


Fig.7

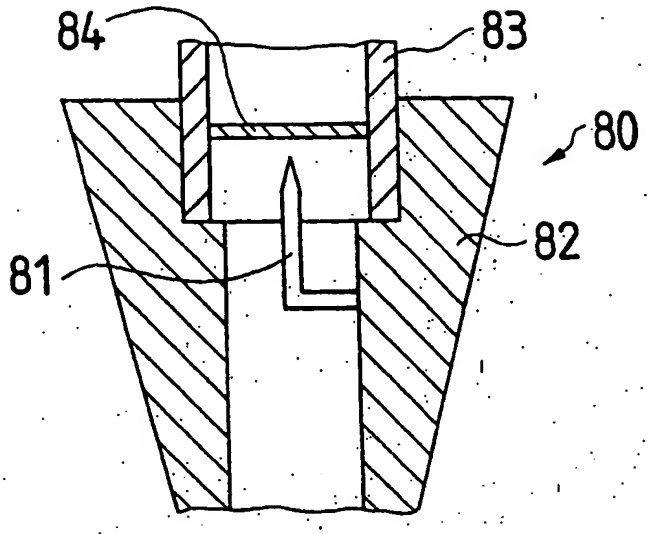


Fig. 8

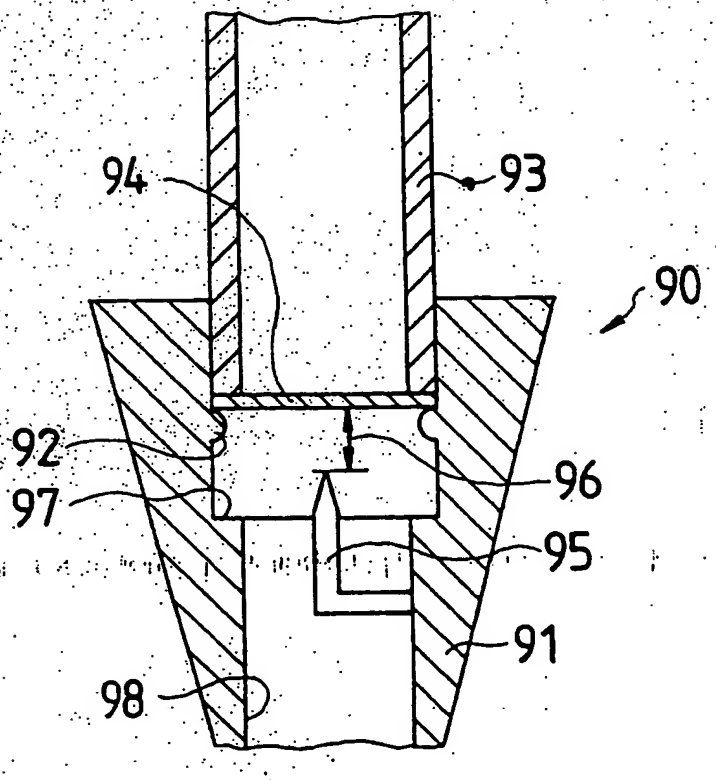


Fig. 9